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Taiwan

Biotechnology

Annual Report

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Report Highlights:

Taiwan has a fairly rational regulatory environment for products derived from biotechnology. The Department of Health (DOH) is the lead agency in granting approval to biotech products intended for food use while the Council of Agriculture (COA) regulates events intended for agricultural use as well as environmental release. Taiwan is still in the process of developing its regulatory system for biotech products. The largest threat to biotech exports is the slow approval process for new-to-market biotech products.

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Executive Summary

Taiwan is the U.S.'s sixth largest agricultural export market. In 2004, the United States exported more than \$2.2 billion of agricultural products to Taiwan, including \$897 million in biotech products. U.S. soybean exports totaled \$302 million, while corn exports were valued at \$594 million. Taiwan is the third largest export market for U.S. corn and fifth largest market for U.S. soybeans.

Taiwan has adopted a fairly rational regulatory environment for products derived from biotechnology. Taiwan's Department of Health (DOH) is the lead agency in granting approval to biotech products intended for food use while the Council of Agriculture (COA) regulates events intended for agricultural use. COA also regulates the field testing and environmental releases of new biotech products.

Biotech food labeling for certain corn and soy products and approval of all corn and soy events became mandatory on January 1, 2003. At the same time, Taiwan began a four-year phase in of mandatory labeling of bioengineered food, beginning with selected soybean and corn products.

Although all currently exported corn and all soy varieties have been approved, the slowness of the food safety assessment process for new-to-market events threatens to disrupt trade in the future. Although Taiwan is considering a new biotech basic law and an import-export regulation, none of these are in final form. Taiwan is also expected to eventually require the registration of all bioengineered foods, not just corn and soybean events.

Although Taiwan's organic food sector continues to expand rapidly, biotech marketing has so far not been a major problem on Taiwan. The local media generally covers the issue in a balanced way.

Biotechnology Trade and Production

Production

Taiwan does not commercially produce any biotech crops.

Development

There are no biotechnology crops under development on Taiwan that are expected to be on the market within the next year. However, several fruit and vegetable varieties will likely enter the market in the next five years.

Imports

Taiwan is the U.S.'s sixth largest agricultural export market. In 2004, the United States exported more than \$2.2 billion of agricultural products to Taiwan, including \$897 million in biotech products. U.S. soybean exports totaled \$302 million, while corn exports were valued at \$594 million. Taiwan is the third largest export market for U.S. corn and fourth largest market for U.S. soybeans.

Food Aid

Taiwan is not a food aid recipient nor is it likely to be one in the near future.

Production of Non-U.S. Approved Varieties

Taiwan does not produce any biotechnology crops that were developed outside of the United States and have not passed through the U.S. regulatory system.

Biotechnology Policy

Regulatory Framework

Taiwan's biotechnology food regulations are based on the Food Sanitation Law, last amended in 2002. However, the law makes no specific mention of biotechnology, which is governed by Department of Health (DOH) regulations.

On Feb. 23, 2001, DOH promulgated regulations on bioengineered food labeling and registration. These regulations applied to soybeans and corn and their products and became effective on January 1, 2003. After this date, no bioengineered soybean and corn may be produced, processed, prepared, packed, and imported or exported unless it has been registered and approved by DOH's Food Sanitation Bureau (FSB).

The Department of Health (DOH) is responsible for food safety risk assessment while Council of Agriculture (COA) has oversight on events to be used in livestock and crop production or aquaculture. COA is also responsible for the environmental risk assessment for new events. The Bureau of Standards, Metrology, and Inspection (BSMI) under the Ministry of Economic Affairs is responsible for import inspection. BSMI currently assists DOH in monitoring grain and oilseed shipments for the presence of biotech events.

To gain DOH food safety approval, a biotech event must be approved by the Genetically Modified Food Safety Advisory Committee (GMFSAC), which is composed of outside experts who evaluate materials submitted by the life science companies. The committee is drawn mostly from the medical and academic communities. Although the process is often slow and cumbersome, deliberations usually follow sound science.

Although Taiwan is considering a new biotech basic law and an import-export regulation, none of these are in final form. Taiwan is also expected to eventually require the registration of all bioengineered foods, not just corn and soybean events.

Although DOH is mostly left to regulate biotechnology without overt political interference, in the past Taiwan's legislature has considered laws that would seriously impair market access for biotech food in Taiwan. Lawmakers may reintroduce a bill into the Legislative Yuan that would effectively ban foods containing biotech events. First proposed in 2002 and again in 2003, the measure was defeated both times. In addition, a law imposing a "compensatory" tax on all products of biotechnology was introduced in 2002, but did not get out of committee. The tax would have been used to indemnify persons for damages caused by biotechnology, but also would have had a chilling effect on biotechnology investment in Taiwan.

Approvals

Below is a list of all biotech products approved on Taiwan for food, feed and processing (FFP). No product has been approved for environmental release (planting).

Table: Taiwan Approved Biotech Products

As of June 30, 2005

CROP	EVENT	COMPANY	DESCRIPTION
Soybean <i>Glycine max L.</i>	<u>GTS 40-3-2</u>	Monsanto Company	Glyphosate tolerant soybean variety produced by inserting a modified 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) encoding gene from the soil bacterium <i>Agrobacterium tumefaciens</i> .
Corn/Maize <i>Zea mays L.</i>	<u>176</u>	Syngenta Seeds, Inc.	Insect-resistant maize produced by inserting the cry1Ab gene from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> . The genetic modification affords resistance to attack by the European corn borer (ECB).
Corn/Maize <i>Zea mays L.</i>	<u>B16 (DLL25)</u>	Dekalb Genetics Corporation	Glufosinate ammonium herbicide tolerant maize produced by inserting the gene encoding phosphinothricin acetyltransferase (PAT) from <i>Streptomyces hygroscopicus</i> .
Corn/Maize <i>Zea mays L.</i>	<u>BT11</u> <u>(X4334CBR,</u> <u>X4734CBR)</u>	Syngenta Seeds, Inc.	Insect-resistant and herbicide tolerant maize produced by inserting the cry1Ab gene from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> , and the phosphinothricin N-acetyltransferase (PAT) encoding gene from <i>S. viridochromogenes</i> .
Corn/Maize <i>Zea mays L.</i>	<u>DBT418</u>	Dekalb Genetics Corporation	Insect-resistant and Glufosinate ammonium herbicide tolerant maize developed by inserting genes encoding Cry1AC protein from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> and phosphinothricin acetyltransferase (PAT) from <i>Streptomyces hygroscopicus</i> .
Corn/Maize <i>Zea mays L.</i>	<u>GA21</u>	Monsanto Company	Introduction, by particle bombardment, of a modified 5-enolpyruvyl shikimate-3-phosphate synthase (EPSPS), an enzyme involved in the shikimate biochemical pathway for the production of the aromatic amino acids.
Corn/Maize <i>Zea mays L.</i>	<u>MON810</u>	Monsanto Company	Insect-resistant maize produced by inserting a truncated form of the cry1Ab gene from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> HD-1. The genetic modification affords resistance to attack by the European corn borer (ECB).
Corn/Maize <i>Zea mays L.</i>	<u>MON863</u>	Monsanto Company	Corn root worm resistant maize produced by inserting the cry3Bb1 gene from <i>Bacillus thuringiensis</i> subsp. <i>kumamotoensis</i> .
Corn/Maize <i>Zea mays L.</i>	<u>NK603</u>	Monsanto Company	Introduction, by particle bombardment, of a modified 5-enolpyruvyl shikimate-3-phosphate synthase (EPSPS), an enzyme involved in the shikimate biochemical pathway for the production of the aromatic amino acids.
Corn/Maize <i>Zea mays L.</i>	<u>T14, T25</u>	Bayer CropScience (Aventis CropScience(AgrEvo))	Glufosinate herbicide tolerant maize produced by inserting the phosphinothricin N-acetyltransferase (PAT) encoding gene from the aerobic actinomycete <i>Streptomyces viridochromogenes</i> .
Corn/Maize <i>Zea mays L.</i>	<u>TC1507</u>	Mycogen (c/o Dow AgroSciences); Pioneer (c/o Dupont)	Insect-resistant and Glufosinate ammonium herbicide tolerant maize produced by inserting the cry1F gene from <i>Bacillus thuringiensis</i> var. <i>aizawai</i> and the phosphinothricin N-acetyltransferase encoding gene from <i>Streptomyces viridochromogenes</i> .

Note: Taiwan event approvals last for five years. These products are approved only for FFP and not for planting.

Field Testing

COA approved guidelines in 1998 for the field-testing of new crops and livestock events. Currently, more detailed regulations are under development.

On January 8, 2002, Taiwan amended its Plant Seed Law by adding a new regulation for bioengineered seeds. Imported planting seed varieties are required to pre-register with the Council of Agriculture (COA). Enforcement rules are not yet available. The commercialization of genetically enhanced animals is governed by the June 1998 "Guidelines for Field Trials of Transgenic Animals", some of which were added to the Animal Husbandry Law in 2001.

Stacked Events

Taiwan is still developing its position on stacked events.

Non-Biotech Coexistence

Taiwan does not yet have a policy on coexistence between biotechnology and non-biotechnology crops.

Labeling

Taiwan's bioengineered food safety approval and labeling regulation took effect on January 1, 2003. Mandatory labeling of bioengineered food was phased in over a two to four year period, beginning with certain soybean and corn products on January 1, 2003. Mandatory bioengineered food labeling took effect on January 1, 2003 for raw soybeans and corn, soybean meal/flour, and corn grit/meal/flour.

Labeling requirements for primary processed soybean and corn food products, such as tofu, soy milk, soy curd, frozen corn, canned corn, soy protein came into effect on January 1, 2004 for. Labeling was required for processed soybean and corn food products from January 1, 2005. The labeling regulations do not apply to products that do not contain pieces of transgene(s) or protein such cornstarch, corn syrup, corn oil, soy oil, and soy sauce. However, labeling may be introduced for other food products in the future.

On all biotech food labels, the Chinese character size should not be smaller than 2x2 mm. The label should be put adjacent to soybean or corn in the finished products ingredients list or in other easily visible place on the package. There is no standard required format. Note: Soybean or corn food products that are not packaged for retail sale are not subject to the GM food labeling requirement – this includes the large volume of products sold in wet markets and restaurants.

Labeling threshold: Taiwan uses a 5 percent tolerance level by weight to determine a product's bioengineered status and for bioengineered food labeling.

Soybean and corn food products made of non-GM materials can be labeled Non-GM or Not-GM Soybean and while corn food products made of non-bioengineered materials may be voluntarily labeled non-Genetically-Modified. The implementation date for voluntary Non-GM food labeling was January 1, 2001. If there is no biotech alternative available, a product may not be labeled "Non-GM". DOH has actually forced the re-labeling of such products as "Non-GMO Coffee."

These rules are in place primarily because Taiwan authorities support a consumer's right to know. They do not see labeling as a food safety issue.

Biosafety Protocol

Taiwan cannot sign the Cartagena Protocol on Biosafety because it is not internationally recognized as a sovereign state. However, in the past, Taiwan has unilaterally implemented some international agreements and is expected to incorporate Cartagena guidelines into its import-export regulation governing biotech products for seeds and planting. COA's Bureau of Animal and Plant Inspection and Quarantine (BAPHIQ) is the lead agency on the issue and serves as Secretariat of Biotech Interagency Task Force under the cabinet, Executive Yuan's Biotech Industry Guidance Committee.

Trade Barriers

There have been no trade disruptions of U.S. biotech product exports. However, Taiwan's approval process has become increasingly slow. The Genetically Modified Food Safety Advisory Committee (GMFSAC) meetings are delayed because members are academics with heavy outside commitments such as giving lectures and grading exams. In addition, since they are not professional regulators, committee members can lack an understanding of the regulatory process. In addition, the process is slowed further since the committee works on the principle of consensus. As a result, the slowness of the food safety assessment process threatens to disrupt trade in the future. The approval process may also delay the introduction of Taiwan-developed products such as biotech rice, fruit and vegetables.

Pending Legislation

The Executive Yuan (Cabinet) is currently reviewing an interagency-proposed comprehensive biotech basic law covering agricultural and pharmaceutical biotechnology development. The law may also areas such as intellectual property rights, the biosafety protocol, as well as food and environmental safety. The law will serve as regulatory framework for all regulations that govern biotechnology. Post will report any concrete details of the new law as they become available.

Technology Fees

Taiwan does not commercially plant any biotech crops.

Marketing Issues**Consumers**

With exception of organic food consumers who are generally skeptical about biotech foods, most consumers are not aware of biotech food. In general, they continue to purchase food in bulk from traditional wet markets and eat traditional Chinese breakfasts with made with biotech soymilk. Despite this, consumption of processed non-biotech food such as soymilk and tofu is gradually increasing because of marketing by local producers and slowly increasing consumer awareness of biotech.

Producers/Importers

As current labeling regulation governs soy or corn food products, some food packers are now promoting foods made of non-GM corn or soybeans. The food producers, who make products in bulk without labeling, generally ignore existence of biotechnology and emphasize their traditional business as usual. Local wheat millers have also warned that they will reject GM wheat while Taiwan feed millers mostly pay attention to trade issues such as biotech product approvals and/or prevention of import disruptions.

Retailers

Except specialty organic food retailing, most of retailing stores stay neutral and provide diversity brands or types food products, both non-biotech and biotech. As of reporting date, there is no country specific study on the marketing on biotech food available.

Capacity Building and Outreach

Past Activities

AIT Taipei has been actively engaged in a series of U.S. Government and USDA-funded capacity building and outreach activities related to agricultural biotechnology. In reverse chronological order, major activities include:

June 2005: Biotech Week. Series of events in Taipei, Tainan and Taichung led by Dr. Kalidas Shetty, U.S. State Department Fellow aimed at facilitating commercialization of Taiwan-developed biotech products, establishing bilateral research linkages and deepening public acceptance of biotech products. Speakers included representatives of three life science companies. Participants included 450 researchers, businesspeople government officials, and general public.

April 2004: Joint U.S. Biotech Regulator Visit to Taiwan. U.S. biotech regulators from EPA, FDA and APHIS visited Taiwan to meet with counterpart Taiwan regulators and held a public seminar on U.S. and Taiwan regulatory system for agricultural biotechnology.

September 2003: Taiwan Media Training Trip to United States. AIT led a delegation of seven Taiwan journalists on an Agricultural Biotechnology Professional Development visit to Washington, DC and St. Louis, MO. The activity aimed to overcome threats to the marketing of U.S. biotech food products by educating the local media on the benefits of agricultural biotechnology as well as its food and environmental safety.

September 2002: Taiwan Media Training Seminar in Taipei. The goal of this seminar was to familiarize Taiwan journalists with agricultural biotechnology issues.

In addition to AIT-led efforts, the U.S. Grain Council and American Soybean Association offices have very active biotech programs on Taiwan. In addition, Taiwan has been conducting a series of public communication programs since July 2004.

There will a seminar in public communication and regulatory capacity building in Taipei in September 2005. AIT will assist in this program by inviting U.S. officials or experts to visit Taiwan and give presentations at the upcoming seminar.

Strategic Considerations

Taiwan's substantial agricultural research infrastructure, sound legal system, favorable climate and very strong information technology base have been it the ability to develop a world-class biotech sector. In addition, a science-based regulatory system and relative lack of anti-biotech protectionist interests has given the public confidence in the safety of biotech foods.

The primary focus is to build upon these strengths by enhancing Taiwan's regulatory capacity and explaining the benefits of biotechnology to the public. AIT has focused heavily on regulatory cooperation, creating linkages between the biotech sectors on Taiwan and in the United States and working with the media. The goal is to enable Taiwan to commercialize its own biotech products, increasing its buy-of the technology. In this vein AIT will continue to share the message that biotech is a "four win" product in that it helps the farmers, the economy, the environment and the consumer.

Reference

Taiwan's GM Food Registration Procedures

To register a biotech food in Taiwan, petitioners must follow the GM Food Registration Regulation, which is outlined below:

GM Food Registration Regulation

- Definition of Genetic Modified Technique

Genetic modification technique is a technique that applies genetic engineering or molecular biology to transfer or insert genetic material into a living cell or organism resulted in genetic modification of the cell or organism. The technique does not include conventional breeding, cell and protoplast fusion, hybridization, mutagenesis, in vitro fertilization, somatic mutations, and chromosome amplification.

- The applicant is required to submit the following information to DOH to register a GM food:

1. The completed registration form.
2. Background information about the applicant.
3. Data on characteristics of the GM food being registered.
4. Synopsis of the GM food's safety assessment.
5. Food safety assessment report on the GM food.
6. Literature list (references and relevant research papers) on the GM food

A one-kilogram sample is required along with an application fee of NT\$100,000, or approximately U.S. \$3,025.

Note: (1) the registration form is available on the DOH website at <http://food.doh.gov.tw>

- With exception of the B5-food safety assessment report and B6-literature, all submitted information must be in Chinese. It has to be typed using specified computer software, font style and size. The DOH requires submitted information both in hard copy and on a 1.44 MB, 3.5" diskette. It has to be printed in A4 size paper.

- If the original information for B1-B4 is in languages other than Chinese, it must then be translated into Chinese by the translation agency or translator registered/recognized by the Taiwan authorities.

- The GM food labeling regulation took effect on January 1, 2003. As of that date all GM soybean and corn foods may not be produced, processed, prepared, packed, and imported or exported, unless they are approved by DOH.

Comment: According to DOH's Food Safety Bureau (FSB), Taiwan's Bioengineered Food Safety Assessment Methods are similar to those used in Japan and U.S. The FSB has also expressed a willingness to accept a Food Safety Assessment package that is submitted to and accepted by advanced countries. End Comment.